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Attorney Docket Number: P30835DIV2C2

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5-31-02*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Pathak et al. May 8, 2002

Serial No.: 10/044,848 Group Art Unit No.: 1615

Filed: January 11, 2002 Examiner: A. Pulliam

For: FORMULATIONS, TABLETS OF PAROXETINE AND PROCESS TO
PREPARE THEM

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY STATEMENT

Enclosed herewith, please find a TERMINAL DISCLAIMER which disclaims, except as provided for therein, the terminal part of any patent granted on the above-identified application which would extend beyond the expiration date of United States Patent No. 6,133,944.

Also enclosed herewith, please find a declaration of Dr. David G. Doughty, an inventor of the presently claimed invention.

Applicants wish to thank the Examiner and Dr. Gollamudi Kishore for the courtesy extended to the undersigned attorney during the Examiner Interview which took place on January 10, 2002. Discussions during the interview primarily centered around the patentability of claims 55 and 56 of the parent application (United States Application No. 09/411,764), which identical subject matter is now presented in claims 16 and 17 of the present application, over the cited references to Barnes (United States Patent No.

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4,721,723), Johnson (WO 92/09281) and Lassen (EP 269 303). It was concluded at the interview that the disclosures of Johnson and Lassen fail to render the subject matter of present claims 16 and 17 unpatentable.

Regarding the reference to Barnes, it was agreed during the interview that the disclosure of Barnes regarding formulations of paroxetine contains no formulation example, paper or actual. Notwithstanding, the Examiner recommended that applicants file a declaration supporting patentable differences between their claimed product and the disclosure in the prior art and show that the differences are a result of the claimed dry process. It was further recommended that the declaration address whether the unexpected results are related to or are dependent upon the excipients used in the dry process.

As indicated in the declaration of Dr. Doughty, all marketed prior tablet formulations of paroxetine were formulated using an aqueous granulation process. On a commercial scale, this process produces unacceptable formulations in that a highly undesirable pink hue is intermittently formed on a batch to batch basis. The current invention is directed to the unexpected discovery that the formulation of paroxetine into tablets can be carried out reliably and on a commercial scale using a formulation process in which water is absent.

It is a well established principal of patent law that unobviousness can reside in the discovery of the cause of a problem, the solution of which employs a combination of old elements. In re Sponnable 160 USPQ 237. The instant invention resulted from the discovery that the undesirable pink hue produced on a batch to batch basis when paroxetine was formulated via a wet granulation process was alleviated when the compound was formulated in the absence of water. Applicants discovery of the problem is unexpected and their solution, using dry processing, is patentably unobvious over Barnes.

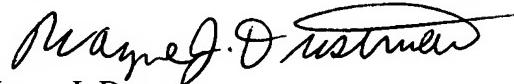
Moreover, it is also shown in the attached declaration of Dr. Doughty, that the instant discovery is related to a formulation process in which water is absent and unrelated to the excipients used.

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Applicants therefore submit that the above remarks and enclosed declaration fully comply with the Examiners' request and recommendations for a showing that the presently claimed compositions are patentably distinct from the formulations disclosed in Barnes, that the differences are a result of the dry processing used for preparation of the presently claimed formulations, and that the differences are unrelated to the excipients used in the process.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number indicated below.

Respectfully submitted,


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